

510(k) SUMMARY

K954758

AUG 19 1997

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations Part 807 (21 CFR § 807), and in particular § 807.92, the following summary of safety and effectiveness information is provided:

Submitted By

Swiss Dental Center
567 Marsh Street
San Luis Obispo, California 93401
Telephone: (805) 541-1004
Telefacsimile: (805) 541-2523
Contact: Carol L. Phillips, D.D.S.
Date Prepared: October 13, 1995

Device Name

Trade or Proprietary Name: Rootform Dental Implant System

Common or Usual Name: Dental Implant

Classification Name: Endosseous Implant (per 21 CFR § 872.3640)

Predicate Devices

510(k)	Sponsor	Device Name
K912262	Intec Corp.	Mini and Universal Implants
K921966	Steri-Oss	HA and TPS Coated Cylindrical Implants
K926101 K926102	Phoenix Dental, Inc.	Opti-Max Dental Implant

Device Description

The Rootform Dental Implant System has two "families" -- one without a hex top with 3.3 mm and 3.8 mm diameter cylinders and a second with a hex lock top with 3.3 mm and 4.0 mm diameters.

The components of each system are as follows:

Rootform 3.3 mm and 3.8 mm Non-Hex Top Implant System

- Implants with internal thread
- Cover screws
- Healing abutments
- Prepable abutments
- Bar or tissue abutments
- Abutment screws
- Tissue abutment with cap
- Prosthetic attachment screws

Rootform 3.3 mm and 4.0 mm Universal Hex Top Implant System

- Implants with internal thread
- Cover screws
- Fixation screws
- Healing abutments
- Straight abutments
- Angled abutments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Les Phillips
Swiss Dental Center
567 Marsh Street
San Luis Obispo, California 93401

AUG 1 9 1997

Re: K954758
Trade Name: Rootform Dental Implant System
Regulatory Class: III
Product Code: DZE
Dated: June 6, 1997
Received: June 12, 1997

Dear Mr. Phillips

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

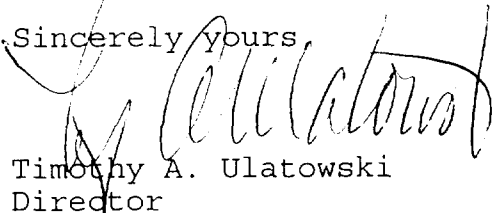
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use

The Rootform Dental Implant is an endosseous dental implant intended to provide support for prosthetic attachments. The Rootform Dental Implant is surgically placed in the bone of the upper or lower jaw arches to provide attachment and support for an abutment and prosthetic devices including artificial teeth, bridges, and dentures.

Comparison to Predicate Devices

The technological characteristics of the current device closely parallel those of the predicate devices. For example, the current device and each of the predicate device implants as well as their associated prosthetic components are manufactured from the same material, titanium alloy (Ti6AL4V). The designs are also similar in that each implant is a two-stage, rootform, cylindrical, press-fit - type implant. As such they share many common features in addition to design principles including surgical implantation and loading procedures and restorative methods and techniques.

Summary of Nonclinical Tests

Not Applicable. The determination of substantial equivalence was not based on an assessment of performance data.

Summary of Clinical Tests

Not Applicable. The determination of substantial equivalence was not based on an assessment of performance data.

Conclusions of Nonclinical and Clinical Tests

Not Applicable

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number _____